JAN 13 2006

K053110

i-STAT CORPORATION

510(k) Summary

Applicant

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Contact person

Paul VanDerWerf, Ph.D.
Director Regulatory Affairs

Date summary prepared

07 October 2005

Summary

Trade Name: i-STAT CHEM8+ Cartridge

Common Name: metabolic panel

This Special 510(k) demonstrates that the modified device (i-STAT CHEM8+ Cartridge), comprising tests for sodium, potassium, chloride, ionized calcium, glucose, urea nitrogen, total carbon dioxide, creatinine, and hematocrit is equivalent to those same tests that are present in the existing i-STAT CG8+, i-STAT EC9+, and i-STAT CREA Cartridges. The i-STAT CHEM8+ Cartridge is intended to be used by medical professionals for the quantitative measurement of sodium, potassium, chloride, ionized calcium, glucose, urea nitrogen, total carbon dioxide, creatinine, and hematocrit in arterial, venous, and capillary blood. The modified device was developed following the requirements for design controls in 21 CFR 820.3. Hazards were identified and the associated risk was evaluated; all unacceptable risks were controlled to an acceptable level by design features and/or labeling. Users needs in the form of design inputs were defined and served as the basis for a design validation. The i-STAT CHEM8+ Cartridge is compatible with the i-STAT Model 300 (i-STAT1) Analyzer.

A comparison of the modified device with the existing un-modified devices shows that the modified device is substantially equivalent in safety and effectiveness. The modified device is not altered with respect to intended use or the technology employed. A table that compares the existing, unmodified devices and the modified device is included.

DESCRIPTION OF THE MODIFIED DEVICE

The modified device is the i-STAT CHEM8+ Cartridge. The modifications comprise a combination of several tests, all of which are on the market and reside in other i-STAT cartridges, into a new panel of tests. The modified device and the cleared devices, together with the tests that are in each cartridge type, are shown in Table 2. The tests that are indicated by an "**X**" in Table 2 are to be incorporated into the modified device. The tests indicated by a "y" are reported in the existing devices but will not be reported in the modified device.

Table 2. Comparison of the Existing, Legally-Marketed, i-STAT Devices with the Modified Device.

	CLEARED DEVICES			MODIFIED DEVICE
TEST/ANALYTE	i-STAT Crea	i-STAT CG8+	i-STAT EC8+	i-STAT CHEM8+
Creatinine	X			X
Ionized Calcium		X		X
Sodium		X	X	X
Potassium		X	X	X
Chloride			X	X
Urea Nitrogen			X	X
Glucose		X	X	X
Hematocrit		X	X	X
PCO_2		y	y	
pH		y	y	
Total CO_2		X	X	X
Anion Gap			X	X
Hemoglobin		X	X	X
Base Excess		y	y	
HCO_3		y	y	
PO_2		y		
sO_2		y		

As is shown in Table 2, the new i-STAT CHEM8+ Cartridge contains a panel comprised of nine reported tests and two calculated tests as is indicated on the labeling for this device. Of these nine reported test, eight tests (glucose, ionized calcium, sodium, potassium, chloride, carbon dioxide, urea nitrogen and creatinine) are commonly referred to as a "basic metabolic panel". The two tests to be reported as calculated parameters are anion gap and hemoglobin.

The performance of the tests contained in the modified (i-STAT CHEM8+) device and in the existing devices are equivalent for all diagnostic purposes. The i-STAT CHEM8+ Cartridge is a single-use device that is to be used with the i-STAT 1 Analyzer. As with other i-STAT Cartridges, two or three drops of venous, arterial or capillary blood is dispensed into the cartridge, the blood are sealed inside the cartridge with the snap closure, and the cartridge is then inserted into the analyzer. The analysis cycle is automatic and is controlled by software in the analyzer. Cartridges are calibrated at the factory. This cartridge is similar in design to the other i-STAT cartridges that are used for the same or similar *in vitro* diagnostic tests. The i-STAT CHEM8+ Cartridge is manufactured using the same process technology and equipment that is used for existing i-STAT cartridges.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Paul VanDerWerf, Ph.D.
Director Regulatory Affairs
i-STAT Corporation
104 Windsor Center Drive
East Windsor, NJ 08520

Re: k053110
Trade/Device Name: i-STAT CHEM8+ Cartridge
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: Class II
Product Code: JGS, CEM, CGZ, JFP, CGA, CGL, JFL, CDS, JPI
Dated: December 16, 2005
Received: December 19, 2005

Dear Dr. VanDerWerf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

i-STAT
CORPORATION

2. INDICATIONS FOR USE

510(k) Number (if known): K053110

Device Name: i-STAT CHEM8+ Cartridge

The i-STAT CHEM8+ Cartridge is useful for monitoring a variety of conditions. The panel of tests is used in the hospital environment to assess kidney function, electrolyte status, acid/base balance, and blood sugar level. This test panel is also used to assess hypertension and hypokalemia.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ann Chappie
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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